

therapeutic sexual dysfunction treatment effect on the administration of the vasoactive, cGMP-PDE inhibiting compounds herein.

The rejection is traversed on the basis that the double patenting reference (08/549,792, hereinafter "the reference") alone provides no basis for it. The process leading to an erection involves sexual stimulation. The nervous system plays a significant part in this overall process. Impairment of the nervous system, as through nerve damage arising from, for example, surgery or a pelvic injury (see Applicants' specification at page 1, lines 23-25) can cause or be associated with sexual dysfunction. The reference contains no suggestion which would cause one of ordinary skill in the art to believe that a male with an injured spinal cord (i.e., an impaired nervous system) would be able to achieve an erection. It discloses the genus of specific compounds useful in the invention, but says nothing about whether the compounds would be useful in treating patients with an injured spinal cord.

Beyond not mentioning the treatment of sexual dysfunction in people with an injured spinal cord, the double patenting reference provides no expectation of success, and the law is emphatic that the prior art must not only provide a suggestion to do what the inventor has done, it must also provide a reasonable expectation of success. The Federal Circuit has explained the proper test:

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success**, viewed in light of the prior art. **Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure** (emphasis added).

In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Clearly, the reference provides no such suggestion. The double patenting rejection should accordingly be withdrawn, and withdrawal is accordingly respectfully requested.

Claims 1-10 stand rejected over WO 94/28902 in view of Doherty, Jr., et al., US patent 6.037,346. It is noted that the WO document is the published International Application corresponding to the double patenting reference used by the Examiner, and Applicants comments from above are incorporated by reference in traversal of the WO document. Doherty relates to local administration of PDE inhibitors for the

treatment of sexual dysfunction and lists neurogenic impotence as one in a long list of the types of impotence which can be treated. Doherty does not, however, provide an expectation of success or the advantages provided by Applicants, in particular the ability to dose orally as opposed to treatment by local administration, from which Doherty clearly teaches away. Moreover, claims 5-10 provide for the treatment of impotence in patients with essentially no residual erectile function following an injury to the spinal cord. Such patients are defined as those who exhibit no apparent erectile response to local stimulation such as penile vibratory stimulation. This is a truly surprising development and one that would not have been expected based on the art cited. That is, it is truly surprising that, even though nerves play a part in the process of obtaining an erection, patients would be able to obtain erections if the nerves are not operative.

In view of the foregoing comments and amendments, it is submitted that this application is in condition for allowance. A Notice of Allowance is accordingly respectfully requested.

Respectfully submitted,

Date: OCT. 25, 2000

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